510 (k) SUMMARY

AUG - 8 2007

Manufacturer and Submitter

Porex Surgical, Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (678) 479-4495

Contact: Jerri Davis
E-mail: jerri.davis@porex.com

Date: May 8, 2007

Trade Name: Device Name: MEDPOR® ATTRACTOR™ Implant

Class: II

Product Code: MQU

510 (k) Number K071335

Substantially equivalent to:

A. MEDPOR ATTRACTOR Magnetic Coupling System
B. MEDPOR Surgical Implant Material; Preformed Cranial & Facial Implants

Device description:

MEDPOR Orbital Implant made of porous polyethylene with a titanium nitride coated stainless steel screw or insert. The screw or insert acts as an attractor to a magnet that is embedded into the posterior of a prosthetic eye. The magnets are gold plated and designed small enough to remain entirely within the prosthesis material of the prosthetic eye, and powerful enough to provide a coupling force between the implant and the prosthesis.

Indications for Use:

The MEDPOR ATTRACTOR Implant is intended for patients who require replacement of volume of an enucleated or eviscerated orbit and who wish to gain improved prosthetic eye motility by coupling the MEDPOR ATTRACTOR Implant to the prosthetic eye.

Technological Characteristics:

A prosthetic eye, which is not part of this device, is created by an ocularist. The ocularist would fit the prosthetic eye in the usual manner. It is advantageous to mechanically couple the prosthetic eye to the implant in some way to improve motility over an uncoupled prosthetic eye. The device that is the subject of this premarket notification uses magnetic force to accomplish the coupling between the MEDPOR ATTRACTOR Implant and the prosthetic eye. During the custom fabrication of the prosthetic eye, by an ocularist, one or more small magnets are placed into the posterior of the prosthetic eye so that the magnets are covered with a thin layer of acrylic. The MEDPOR ATTRACTOR Implant is covered with tissue when the surgeon implants it in the patient's enucleated or eviscerated orbit. When the prosthetic eye is placed on the implant, the magnet force between the magnets in the prosthetic eye and the MEDPOR ATTRACTOR Implant provide a coupling force to improve the movement of the prosthetic eye.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2007

Porex Surgical, Inc.
c/o Mr. Jerri Davis
15 Dart Road
Newman, GA 30265

Re: K071335
Trade/Device Name: MEDPOR® ATTRACTOR™ Implant
Regulation Number: 21 CFR 886.3320
Regulation Name: Implant with Titanium Coated Stainless Steel Screw or Insert
Regulatory Class: II
Product Code: HPZ
Dated: July 30, 2007
Received: July 31, 2007

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Applicant: Porex Surgical Inc.
15 Dart Road
Newnan, GA 30265

Tel: (678) 479-1610
Fax: (678) 423-1437

510(k) Number: K071335

Trade Name: Device Name: MEDPOR® ATTRACTOR™ Implant

Indications for Use:

The MEDPOR ATTRACTOR Implant is intended for patients who require replacement of volume in an enucleated or eviscerated orbit and who wish to gain improved prosthetic eye motility by coupling the MEDPOR ATTRACTOR Implant to the prosthetic eye.

Prescription Use ___X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

H. Viraj

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K071335